DETAILED ACTION

1. This office action is responsive to Applicant's arguments filed on February 19, 2008. Examiner acknowledges the amendments to claims 10, 12 and 14 and the cancellation of claim 11 and addition of new claims 15-26. Currently claims 10 and 12-26 are pending.

Response to Arguments

2. Applicant's arguments see page 8, lines 2-5, filed on February 19, 2008, with respect to claim 12 have been fully considered and are persuasive. The objection of claim 12 has been withdrawn.

3. Applicant's arguments see page 8, lines 6-12, filed on February 19, 2008, with respect to claims 10-14 have been fully considered and are persuasive. The rejection of claims 10-14 under 35 USC 112 second paragraph has been withdrawn.

4. Applicant's arguments, see pages 8-12, filed on February 19, 2008, with respect to the rejection(s) of claim(s) 10-14 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found art and the amended claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10, 12, 15, 19, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,191,893 to Reiten (Hereinafter "Reiten").

In reference to claims 10 and 19:

Reiten teaches a volume variation sensor for monitoring obstructive sleep apnea, which comprises an elongated tubular enclosure with a thin deformable wall (Abstract). The tubular sensor is wrapped around the patient's chest (Fig. 1) for following body movements caused by the user's lung operation (Col. 5, lines 17-30). A sensor is used for sensing fluctuations in a user's lung operation (Col. 3, lines 1-10). The sensor is attached to a pressure monitoring apparatus (14) for determining successive values representative of the user's lung fluctuations and for translating values into appropriate lung-evaluating information (the device is capable of detecting sleep apnea based on the change in the volume and pressure inside the tubular belt, Col. 2, lines 40-46). The belt comprises at least one chamber (21 and 15) formed between an inner wall (The side near element 10) and at least one an outer wall (Fig. 3, the opposite side of 10). The chamber has a substantially enclosed volume of gas disposed therein (Col. 3, lines 21-33).

The chamber is sized and shaped so as to span the entire lung region of the user's body (Fig. 1). The inner wall follows the displacement of the entire lung region (Fig. 5). The inner wall and the outer wall combine to compress the volume of gas as the inner wall is pushed towards the outer wall during inspiration as the lungs expand and to decompress the volume of gas as the inner wall relaxes during expiration as the lungs contract (Col. 5, lines 17-30). The sensor is directly exposed to the enclosed volume for sensing changes in pressure within the chamber throughout inspiration and expiration (the pressure monitoring aperture is connected to the chamber 15 via tube 13).

In reference to claims 12 and 21:

A seal (Fig. 4, the airtight chamber 15 is sealed) for sealing the chamber (the chamber 15) is connected to the tube 13 which is connected to the pressure aperture 14, and the chamber 15 is airtight, the aperture will detect the changes in pressure inside the chamber in order to determine sleep apnea, Col. 3, lines 2-6 and Col. 5, lines 17-30).

In reference to claims 15 and 24:

The item comprises a front panel (the front of the belt, including the buckle) and a rear panel (the rest of the belt), where the chamber is disposed in the rear panel (Fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 13-14 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiten in view of US 4,559,953 to Wright et al (Hereinafter "Wright").

In reference to claims 13-14 and 22-23:

Reiten teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

However, Reiten fails to teach that:

> The inner wall is substantially resilient and the outer wall is substantially rigid in relation to the inner wall. The inner wall may follow, in use, the movement caused by the user's lung operation whilst the outer wall remains substantially rigid.

Wright teaches:

> An apparatus is used for detecting and measuring changes in the shape of a wall of a chamber. The device includes a detector capsule adapted for attachment to the wall and pneumatically connected to a volume transducer responsive to changes in the

internal volume produced by changes in the shape of the wall (Abstract of Wright). The capsule (1 of Wright) comprises a cup shaped rigid body (2 of Wright), which may be made of metal or any suitable rigid plastic material which is closed by a resiliently deformable material (diaphragm 3 of Wright). The diaphragm may be any plastic material such as polyurethane (Col. 1, lines 59-68 and Col. 2, lines 28-44 of Wright).

It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the tubular chamber of Reiten with a capsule and a transducer similar to the one taught by Wright in order to monitor respiration activities in neonates or adults, as has been explicitly taught by Wright (Col. 1, lines 10-13). Substituting one known element with another element would have yielded predictable results.

9. Claims 16-17 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiten in view of US 5,159,935 to Sackner et al (Hereinafter "Sackner").

In reference to claims 16 and 25:

Reiten teaches all of the claim limitations; see the rejection of claims 10 and 10 above.

Reiten also discloses that other known devices are used for monitoring the volume changes along the torso of a subject, including impedance pneumography and inductive plethysmography which are expensive methods and may also pick up unwanted signals such as cardiac events (Col. 1, lines 40-45 of Reiten). Reiten also teaches using two belts for monitoring the chest and abdominal volume displacement within the patient's body (Fig. 1 of Reiten).

However, Reiten fails to teach that:

> At least one chamber comprises two chambers each of which correspond to a lung and that each chamber is positioned over a separate lung when the item is worn over the body of the user.

Sackner teaches:

> A non-invasive estimation of individual lung function (Abstract of Sackner), which comprises transducers (12 and 14 of Sackner) that are placed on different sections of the torso in order to measure the changes of the volume of the underlying lungs (Abstract and Fig. 1A of Sackner). As disclosed in Figs. 12A, 12C, 13A and 13B the inductive transducers can be placed at different locations on the patient's body in order to monitor each lung separately.

As disclosed by Reiten in order to reduce the cost and reduce the error in monitoring volume displacement within the patient's lung, one can replace the inductive transducers with the tubular belt of Reiten (Col. 1, lines 40-

68 of Reiten). Therefore it would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have replaced the multiple transducers of Sackner (as disclosed in Figs. 12A, 12C, 13A and 13B of Sackner) with the air tube belt of Reiten in order to monitor the respiration of the patient to study sleep apnea and to also be able to monitor each lung separately.

In reference to claims 17 and 26:

Reiten teaches all of the claim limitations; see the rejection of claims 10 and 10 above.

Reiten also discloses that other known devices are used for monitoring the volume changes along the torso of a subject, including impedance pneumography and inductive plethysmography which are expensive methods and may also pick up unwanted signals such as cardiac events (Col. 1, lines 40-45 of Reiten). Reiten also teaches using two belts for monitoring the chest and abdominal volume displacement within the patient's body (Fig. 1 of Reiten).

However, Reiten fails to teach that:

> At least one chamber comprises four chambers each of which correspond to one of an upper rib region and a lower rib region of a lung. The four chambers configured so that two of the four chambers are respectively positioned over an upper rib region and

> a lower rib region of a lung, and the other two of the four chambers are respectively positioned over an upper rib region and a lower rib region of the other lung when the item is worn over the body of the user.

Sackner teaches:

> A non-invasive estimation of individual lung function (Abstract of Sackner), which comprises transducers (12 and 14 of Sackner) that are placed on different sections of the torso in order to measure the changes of the volume of the underlying lungs (Abstract and Fig. 1A of Sackner). As disclosed in Figs. 12A, 12C, 13A and 13B the inductive transducers can be placed at different locations on the patient's body in order to monitor each lung separately.

As disclosed by Reiten in order to reduce the cost and reduce the error in monitoring volume displacement within the patient's lung, one can replace the inductive transducers with the tubular belt of Reiten (Col. 1, lines 40-68 of Reiten). Therefore it would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have replaced the multiple transducers of Sackner (as disclosed in Figs. 12A, 12C, 13A and 13B of Sackner) with the air tube belt of Reiten in order to monitor the respiration of the patient to study sleep apnea and to also be able to monitor each lung separately.

10. Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiten.

In reference to claims 18 and 20:

Reiten teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

However, Reiten fails to explicitly teach that:

A feedback means or means for capturing and evaluating comprises at least one of: a microprocessor, a computer, and a data logger.

Reiten discloses that the pressure measurement registered by the pressure apparatus (14 of Reiten) can be displayed and used in order to determine sleep apnea in a patient (Fig. 6A). Even though Reiten fails to explicitly teach the use of a processor or computer for generating these graphs, it is inherent that a processing means must have been used in order to save and present the collected pressure values by each sensor (11 and 12 of Reiten).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/11/2008